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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/706,301	11/03/2000	Koichi Saito	207198	6724

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EXAMINER
EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
1644	12

DATE MAILED: 11/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/706,301	Applicant(s) Saito et al.
	Examiner G.R. Ewoldt	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Aug 5, 2002 .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-15 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6, 7
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of the species: "a fatty acid ester derived from oleic acid and alcohol" as the oil component (A), and "oleate" as emulsifiers (B) and (D), in Paper No. 11, filed 8/05/02, is acknowledged. Applicant's traversal is on the grounds that a search of all the species would pose no undue burden on the Examiner. Upon further consideration the species requirement has been withdrawn.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention.

The instant invention is drawn to a vaccine. Accordingly, the specification must disclose both how to make, and how to use, all the vaccines that would be encompassed by the instant claims. It is noted that independent Claim 1 recites only the limitations that the vaccines comprise a wide range of percentages of polyethylene glycol (PEG) derivatives, of a wide range of molecular weights, represented by a chemical formula itself comprising two variable R groups and a variable polymerization degree. It would seem then that the claim encompasses a virtually unlimited number of vaccines. Several of the dependent claims recite a number of additional limitations, e.g., a range of molecular weights (Claim 2) or a narrowing of the percentages

of PEG (Claim 3), however, these limitations do not significantly reduce the number of vaccines encompassed by the claims. Other of the dependent claims recite product by process limitations, e.g., Claim 4, however, it is unclear just how many vaccines might be encompassed by these claims. In support of the broad range of vaccines of the claims the specification discloses an array of Examples and Comparative Examples (the difference between which is unclear) that appear to disclose techniques for producing some of the vaccines presumably encompassed by the instant claims. While it appears that Example 1 discloses a method for producing vaccine component W/O-1, the Example insufficiently discloses how the complete product of the instant claims, i.e., a complete vaccine, is produced. Note that a disclosure of a single sentence, "Thereto [W/O-1] was added gradually the antigen suspension with stirring and mixed by stirring at 12,000 rpm for 5 min at normal temperature in CLEARMIX CLM-0.8S (M TECHNIQUE) to give a W/O type emulsion (W/O-1)," cannot be considered enabling for the production of a complete vaccine. Further, it is unclear just how W/O-2-4 are produced, nor how any of the complete vaccines comprising said adjuvant component are made. Again, a disclosure of "The W/O type emulsion (W/O-1, 1 part) prepared in Example 1 and the outer aqueous phase 2 (1 part) prepared according to the composition of the outer aqueous phase 2 in Table 3 were weighed and an oil adjuvant vaccine 2 was prepared," is insufficient to allow one of skill in the art to prepare the vaccines encompassed by the instant claims. Thus, the production of the vaccines of the instant claims must be considered highly unpredictable and requiring of undue experimentation.

The specification additionally discloses a number of Experimental Examples (it is unclear just how an Experimental Example differs from an Example or a Comparative Example) disclosing the use of the vaccines of the instant claims. It is noted, however, that only Experimental Example 1 actually discloses the efficacy of any of the vaccines of the instant claims. It is further noted that said Example discloses the use of vaccines of unknown composition (see preceding paragraph) comprising a single antigen (swine erysipilas). The additional Experimental Examples appear to disclose data relating the safety of the vaccines, however, safety data lends little additional support. Accordingly, in view of the breadth of the instant claims, the single relevant example is considered insufficient to disclose to one of skill in the art the use of the vaccines of the instant claims.

In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In view of the quantity of experimentation necessary, the lack of sufficient working examples, the unpredictability of the art, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

4. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar* , 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of a W/O/W type oil adjuvant vaccine as recited in the claims. The specification discloses an essentially indecipherable method for producing the vaccines encompassed by the instant claims (see paragraph 3). Said method additionally fails to disclose the specific components of any of the vaccines encompassed by the instant claims. The mere recitation of vague limitations such as a PEG phase of between 0.5 - 20% wt% (Claim 1), or an oil phase component which becomes liquid at room temperature (Claim 4), or an emulsifier which has an HLB of less than 10 (Claim 12), is insufficient to describe the vaccines of the instant claims. Additionally, given the breadth of the claims (see paragraph 3), one of skill in the art must conclude then that the specification fails to disclose a representative number of species to describe the claimed genus. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner

by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The CM1 Fax Center telephone numbers are 703-872-9306 (before final) and 703-872-9307 (after final).

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
October 31, 2002